

REMARKS

Status of the Claims

The present Office Action addresses claims 1-35, however claims 13, 14, 19, 20, 24, and 32 are withdrawn from consideration. Remaining claims 1-12, 15-18, 21-23, 25-31, and 33-35 stand rejected.

Amendment to the Claims

Applicant amends claim 1 to recite that the closure mechanism is adapted to receive a locking mechanism that *directly* engages the bore. Support for this amendment can be found throughout the specification, for example in paragraph [0041] of the published application. No new matter is added. Applicant respectfully requests entry of this amendment after final as the amendment does not raise any new issues and places the application in condition for allowance, as discussed below, or at least in better condition for appeal.

Rejections Pursuant to 35 U.S.C. § 102

Claims 1-12, 15, 18, 21-23, 25-31, and 33 are rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,136,002 (“Shih”). Applicant respectfully disagrees.

Claims 1-12, 15 and 18

Independent claim 1 recites a spinal anchoring element adapted to seat first and second spinal fixation elements at a distance spaced apart from one another, and having a bore extending therethrough. Claim 1 further recites a fastening element adapted to extend through the bore to mate the spinal anchoring element to bone and a closure mechanism adapted to mate to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element. The closure mechanism is adapted to receive a locking mechanism that directly engages the bore.

Shih does not teach or suggest a spinal anchoring element having a bore extending therethrough, a fastening element adapted to extend through the bore to mate the spinal anchoring element to bone, and a closure mechanism adapted to receive a locking mechanism that *directly*

engages the bore in the spinal anchoring element. The Examiner appears to agree that Shih does not teach or suggest a locking mechanism that *directly engages* the bore by repeatedly stating that “the term ‘engages’ does not require direct contact” in presenting this rejection. Office Action page 5, ¶ 2; page 2, ¶ 3. While Applicant disagrees with the Examiner’s interpretation, amended claim 1 requires direct engagement. It is clear from at least Figures 2 and 3 that Shih’s locking nut (S), which the Examiner likens to the claimed locking mechanism, does not directly engage the screw hole (124), which the Examiner likens to the claimed bore. Claim 1 therefore distinguishes over Shih.

Applicant further notes that Shih’s device is not capable of performing the claimed function. The Examiner argues on page 5 of the Office Action that “adapted to” recitations in the claims are “being interpreted as functional language, and that the Shih et al. reference need merely be capable of performing the claimed function.” The universal cover plate (14), which the Examiner likens to the claimed closure mechanism, is not capable of receiving a locking mechanism that *directly engages* the bore in the spinal anchoring element. The locking nut (S), or any other element the cover plate (14) could receive through the cover plate’s central opening, is necessarily threaded into the hole (H) in the vertebral plate (12), separate from and not in direct engagement with the screw hole (124). Moreover, the screw hole (124) does not align with any element of the cover plate (14) so as to allow the cover plate (14) to receive a locking mechanism adapted to directly engage a screw hole (124). Indeed, the cover plate (14) secures the rods (40) against the heads (BH) of the screws (B), so both the rods (40) and the screws (B) provide a barrier between the cover plate (14) and any locking mechanism the cover plate (14) could receive that could directly engage the screw holes (124).

Accordingly, claim 1, as well as claims 2-12, 15, and 18 which depend therefrom, distinguish over Shih and represent allowable subject matter.

Claims 21-23, 25-31, and 33

Independent claim 21 recites first and second flexible spinal fixation elements and a plurality of spinal anchoring devices adapted to mate to a plurality of vertebrae and to engage the first and

second spinal fixation elements such that the first and second spinal fixation elements can be tensioned between the plurality of spinal anchoring devices to adjust a position of the plurality of vertebrae in both a sagittal plane and a coronal plane when the plurality of spinal anchoring devices are implanted in a plurality of vertebrae. At least one of the spinal anchoring devices is adapted to receive a fastening element for mating the spinal anchoring device to bone and a closure mechanism axially aligned with the fastening element to lock the first and second spinal fixation elements to the spinal anchoring device.

Shih does not teach or suggest that at least one of the spinal anchoring devices is adapted to receive a closure mechanism *axially aligned* with a fastening element. It does not appear that the Examiner responded to this argument previously presented by Applicant, and Applicant maintains that Shih's cover plate (14) is not axially aligned with a screw (B), which the Examiner likens to the claimed fastening element. Figures 2 and 3 of Shih clearly show that the cover plate (14) is centered in the vertebral plate (12) while the screws (B) are offset from the center. The locking nut (S) is inserted in the hole (H) in the center of the vertebral plate system (10), and two screws (B) are inserted through two separate bores (124) in rod-seating channels. The cover plate (14) is simply not axially aligned with either or both of the screws (B) and cannot be axially aligned even if one desired as such. Thus, Shih does not disclose a device that is capable of functioning as claimed.

Accordingly, claim 21, as well as claims 22, 23, 25-31, and 33 which depend therefrom, distinguish over Shih and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. § 103

Claims 16-17, and 34-35 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Shih in view of U.S. Publication No. 2004/0236327 ("Paul"). At least for the reasons explained above, Shih does not anticipate independent claims 1 and 21 from which claims 16-17 and 34-35 respectively depend. Paul is only relied on for dependent claim features, namely that a spinal fixation element can be flexible and can be formed from a bioabsorbable material. Paul does not remedy the deficiencies of Shih because Paul likewise fails to disclose a closure mechanism adapted to receive a locking mechanism that directly engages a bore in a spinal anchoring element. Paul also fails to disclose that at least one of the spinal anchoring devices is adapted to receive a closure

mechanism axially aligned with a fastening element. Accordingly, claims 16-17 and 34-35 are allowable at least because they depend from an allowable base claim.

Conclusion

Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant's amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Dated: July 23, 2008

Respectfully submitted,

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